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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,413	03/30/2001	Shigeru Yamamoto	Q63731	8678
7590 11/01/2005 Sughrue Mion Zinn Macpeak & Seas 2100 Pennsylvania Avenue NW Washington, DC 20037			EXAMINER STEADMAN, DAVID J	
			ART UNIT 1656	PAPER NUMBER
DATE MAILED: 11/01/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,413

Applicant(s)

YAMAMOTO ET AL.

Examiner

David J. Steadman

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,11,13,14,22,24 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 22 is/are allowed.
- 6) ☒ Claim(s) 1,2,11,13,14,24 and 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/8/05;5/11/05;8/18/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1]** The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.
- [2]** Claims 1-2, 4, 11, 13-14, 22, 24, and 26-30 are pending in the application.
- [3]** Applicants' amendment to the claims, filed on 8/18/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [4]** Receipt of information disclosure statements (IDSs), filed on 5/11/2005 and 8/18/2005, is acknowledged.
- [5]** Receipt of a statement directing entry of the substitute sequence listing into the specification, filed on 8/18/2005, is acknowledged.
- [6]** Applicants' arguments filed on 8/18/2005 have been fully considered.
- [7]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Information Disclosure Statement

- [8]** The reference of Hoesel et al. has been considered in the IDS filed on 3/8/2005. A copy of Form PTO/SB/08 is attached to the instant Office action.
- [9]** All references cited in the IDS filed on 5/11/2005 have been considered by the examiner. A copy of Form PTO/SB/08 is attached to the instant Office action.

[10] The IDS filed on 8/18/2005 appears to be an exact duplicate of the IDS filed on 3/8/2005 and has been treated as such. As all references cited in the 3/8/2005 have been considered, the references cited in the 8/18/2005 IDS have been lined through as being duplicate citations.

[11] If the examiner has inadvertently overlooked an IDS that has previously been filed in the instant application, applicants' cooperation is requested in alerting the examiner to this IDS in the response to this Office action.

Claim Objections

[12] Applicant is advised that should claims 27 or 28 be found allowable, claim 29 or 30 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, Second Paragraph

[13] The rejection of claims 1-2, 11, 13-14, 24, and 26 under 35 U.S.C. 112, second paragraph is maintained for the reasons of record and the reasons stated below. Newly added claims 27-30 are included in the instant rejection. Thus, claims 1-2, 11, 13-14, 24, and 26-30 are rejected.

RESPONSE TO ARGUMENT: Applicants argue the intended meaning of the term “naturally occurring” is based on its plain and ordinary meaning, *i.e.*, “wild-type polypeptides found naturally in the recited microorganisms, and do not encompass non-naturally occurring proteins such as endogenously expressed mutants generated by UV and/or chemical mutagenesis, or recombinantly expressed variants.” Applicants argue that in view of the plain meaning of the term “naturally occurring,” the term is definite.

Applicants' argument is not found persuasive. The examiner acknowledges applicants' intended meaning of the term “naturally occurring.” However, even in view of applicants' intended meaning of “naturally occurring” with respect to a polypeptide, it remains unclear as to how a skilled artisan distinguishes those polypeptides that exhibit all of the recited characteristics of the claims, *i.e.*, has an activity to act upon a disaccharide glycoside, has enzymatic activity at pH 2.5 to 3, is stable at 50 degrees Celsius or less, has a MW of 47 kDa, and hybridizes to SEQ ID NO:7, that are considered to be “naturally occurring” from those that are not. The claimed or recited polypeptide is not limited to those that are endogenously expressed by the recited microorganism, particularly as the specification makes clear that the invention encompasses recombinantly expressed polypeptides (see, *e.g.*, pp. 12-13 of the specification). Thus, in accordance with MPEP 2111, the examiner has interpreted the claims as encompassing those polypeptides that are endogenously expressed by the recited microorganism and those polypeptides that are expressed as a result of recombinant expression using the recited microorganism as an expression host. The specification provides no guidance that would allow a skilled artisan to determine, with a

Art Unit: 1656

reasonable degree of confidence, whether a polypeptide isolated from an *Aspergillus* microorganism or isolated from *A. oryzae*, *A. niger*, *A. aculeatus* and having the recited characteristics occurs naturally. If a polypeptide having all of the recited characteristics of the claims is isolated from the recited microorganism(s), it remains unclear as to what physical and/or functional characteristics distinguish those polypeptides that are considered to be "naturally occurring" from those polypeptides that are not "naturally occurring," including those polypeptides that are "non-naturally occurring proteins such as endogenously expressed mutants generated by UV and/or chemical mutagenesis, or recombinantly expressed variants." In the absence of such identifying characteristics, it is unclear as to how a skilled artisan determines the metes and bounds of the claimed or recited polypeptides. It is suggested that applicants clarify the meaning of the claims.

Claim Rejections - 35 USC § 112, First Paragraph

[14] The new matter rejection of claims 1-2, 11, 13-14, 24, and 26 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. Newly added claims 27-30 are included in the instant rejection. Thus, claims 1-2, 11, 13-14, 24, and 26-30 are rejected.

RESPONSE TO ARGUMENT: Applicants argue: (1) diglycosidase enzymes from *A. oryzae*, *A. niger*, *A. aculeatus*, and *A. fumigatus* have been isolated and characterized, referring to p. 45, Table 6; (2) the hybridization results at p. 70, Example 10 demonstrate that the diglycosidases of *A. oryzae*, *A. niger*, and *A. aculeatus* are structurally similar to that of *A. fumigatus*; and (3) based on the alleged close

relationship between microorganisms in the genus *Aspergillus*, a skilled artisan would have considered all diglycosidase enzymes as encompassed by the claims to have the recited characteristics.

Applicants' argument is not found persuasive. The issue is not whether a representative number of species of the claimed or recited polypeptides has been disclosed, but rather that the original application fails to provide support for certain limitations of the claimed or recited polypeptides. The examiner maintains that applicants have failed to "show support" for certain recited limitations in the claims. See pp. 5-7 of the 5/18/2005 Office action. In view of this failure to "show support" in accordance with MPEP 2163, these limitations are considered to be new matter. It is suggested that applicants show support for these limitations in the claims.

[15] The written description rejection of claims 1-2, 11, 13-14, 24, and 26 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. Newly added claims 27-30 are included in the instant rejection. Thus, claims 1-2, 11, 13-14, 24, and 26-30 are rejected.

RESPONSE TO ARGUMENT: Applicants argue: (1) diglycosidase enzymes from *A. oryzae*, *A. niger*, *A. aculeatus*, and *A. fumigatus* have been isolated and characterized, referring to p. 45, Table 6; (2) the hybridization results at p. 70, Example 10 demonstrate that the diglycosidases of *A. oryzae*, *A. niger*, and *A. aculeatus* are structurally similar to that of *A. fumigatus*; and (3) based on the alleged close relationship between microorganisms in the genus *Aspergillus*, a skilled artisan would

Art Unit: 1656

have considered all diglycosidase enzymes as encompassed by the claims to have the recited characteristics.

Applicants' argument is not found persuasive. As noted in a previous Office action, the issue is whether the single disclosed species of SEQ ID NO:8 is representative of all "naturally occurring" polypeptides as encompassed by the claims. The genus of claimed polypeptides, *i.e.*, "naturally occurring" polypeptides, encompasses a subgenus of those polypeptides having the recited characteristics that are both "naturally occurring" and non-naturally occurring. As noted in a previous Office action, the Court of Appeals for the Federal Circuit has held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." UC California v. Eli Lilly, (43 USPQ2d 1398). The CAFC has also held that "A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials" Amgen Inc. v. Chugai Pharmaceutical Co. Ltd. (18 USPQ2d 1016). In this case, the specification fails to disclose those structural and/or functional characteristics of the claimed genus of polypeptides that distinguish the genus of "naturally occurring" polypeptides from the larger genus of naturally occurring and non-naturally occurring polypeptides.

Given the lack of description of a representative number of polypeptides, the specification fails to sufficiently describe the claimed invention in such full, clear,

Art Unit: 1656

concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

In order to clarify the record, the following comments are provided, which address applicants' arguments (1) to (3) above. Regarding argument (1), while the specification discloses that crude cell extracts of particular strains of *A. oryzae*, *A. niger*, *A. aculeatus* exhibited diglycosidase activity (see Table 6 at p. 45), it is noted that only the diglycosidase of SEQ ID NO:8, isolated from *A. fumigatus*, has been "isolated and characterized." Regarding argument (2), the examiner acknowledges the specification's disclosure that a "signal was detected" in a hybridization reaction between isolated chromosomal DNA of *A. oryzae*, *A. niger*, *A. aculeatus* and SEQ ID NO:7. However, it should be noted that there is no indication in the specification as to how structurally similar the nucleic acids may be. Regarding argument (3), while applicants argue that one would expect that all *Aspergillus* microorganisms would produce diglycosidase enzymes that have the recited characteristics, there is no evidence of record to support this assertion.

Conclusion

[16] Status of the claims:

Claims 1-2, 4, 11, 13-14, 22, 24, and 26-30 are pending.

Claims 4 and 22 appear to be in a condition for allowance.

Claims 1-2, 11, 13-14, 24, and 26-30 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

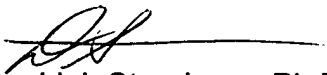
Art Unit: 1656

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs, 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656